

510(k) Summary LPS Metaphyseal Sleeve

A. Contact Person:

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JUL 09 2004

B. Device Information:

Trade Name:	LPS Metaphyseal Sleeve (Limb Preservation System)
Common Name:	Total Knee Prosthesis
Classification Name and Regulatory Class:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis: Class II per 21 CFR §888.3560
Product Code:	87 JWH

C. Indications for Use:

The metaphyseal sleeve is intended for use in primary and revision knee joint replacement and in oncology cases. The metaphyseal sleeve is used to fill metaphyseal defects in the distal femur and joins a knee femoral component with an intramedullary stem. The sleeve may be used across several product lines: the Limb Preservation System (LPS), the S-ROM system, and the fixed platform portion of the P.F.C. Sigma system. The previously cleared indications for use for these systems:

The LPS is intended for use in replacement of the mid-shaft portion of the femur, proximal, distal and/or total femur, and proximal tibia, especially in cases that require extensive resection and replacement. Specific diagnostic indications for use include:

- malignant tumors (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) requiring extensive resection and replacement;
- patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis, requiring extensive resection and replacement;
- revision cases for a failed previous prosthesis requiring extensive resection and replacement;
- severe trauma requiring extensive resection and replacement.

The LPS is also intended for use in bone loss post-infection, where the surgeon has elected to excise the bone and replacement is required.

The metaphyseal sleeve, the distal femoral component, the tibial components, and the non-porous coated straight and bowed stems are intended for cemented use only.

510(k) Summary (continued) LPS Metaphyseal Sleeve

C. Indications for Use (continued):

The S-ROM Modular Total Knee System was cleared as the "NOILES Posterior Stabilized Knee."

The NOILES Posterior Stabilized Knee is indicated for use with PMMA bone cement in primary or revised cases in patients:

- who have reached skeletal maturity and
- for whom the surgeon has decided to resect both cruciate ligaments or whose cruciate ligaments are absent or incompetent due to the following conditions: rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, and arthritis secondary to a variety of diseases and anomalies, failure of a previous knee reconstruction procedure, trauma.

The P.F.C.® Sigma Knee System is indicated for use as a total knee replacement for patients suffering from severe pain and disability due to permanent structural damage in the knee joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, or pseudogout.

This damage may also be a result of trauma or failed prior surgical intervention.

The P.F.C.® Sigma Knee System is indicated for use with polymethylmethacrylate (PMMA) bone cement.

D. Device Description:

The metaphyseal sleeve is a component to the previously cleared Limb Preservation System (LPS). The titanium sleeve is used to fill metaphyseal defects in the distal femur and joins a knee femoral component with an intramedullary stem. The sleeve is cone-shaped, with an outer stepped anatomical taper to fill the metaphyseal region of the distal femur. All but the final four steps of the sleeve are porous coated. The sleeve ranges in size from 31 to 46mm, as measured at the widest (M/L width) portion of the sleeve.

Through the use of adapters, the sleeve is compatible on its proximal and distal ends with femoral stems and distal femoral components. The femoral stems and distal femoral components are from previously cleared DePuy knee systems such as the Limb Preservation System, the S-ROM® NOILES Total Knee System and the fixed platform of the P.F.C. Σ System.

On the distal end, the sleeves either mate directly with the posts on previously cleared femoral components (e.g., the S-ROM femoral) or, through the use of one of the two wrought cobalt chrome femoral to sleeve adapters, mate with previously cleared femoral components that do not have posts (e.g., the LPS femoral, the P.F.C. Σ TC3 or the P.F.C. Σ PS femoral). These adapters will be available in 3 offsets: +0, +5 and +10 millimeters.

On the proximal side, the sleeves mate with previously cleared stems, either directly (when using an S-ROM stem) or through the use of the titanium LPS P.F.C. Stem to Sleeve Adapter (when using a P.F.C. type fluted or cemented stem).

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E. Substantial Equivalence:

The substantial equivalence of the LPS is substantiated by its similarity:

- in sterilization, packaging and indications for use to the LPS (K003182 cleared on June 27, 2001).
- in design, materials and indications for use to the femoral sleeve found in the S-ROM/Noiles PS Total Knee System (K870730 cleared on May 26, 1987).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JUL 09 2004

Re: K040281

Trade/Device Name: LPS Metaphyseal Sleeve

Regulation Number: 21 CFR 888.3560

Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Regulatory Class: II

Product Code: JWH

Dated: June 1, 2004

Received: June 3, 2004

Dear Ms. Weissman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

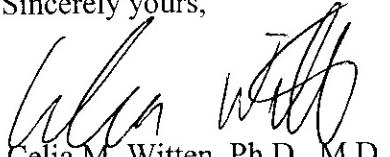
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K040281**

Device Name: **LPS Metaphyseal Sleeve**

Indications for Use:

The metaphyseal sleeve is used to fill metaphyseal defects in the distal femur and joins a knee femoral component with an intramedullary stem. The metaphyseal sleeve is intended for use in primary and revision knee joint replacement and in oncology cases across several product lines: the Limb Preservation System (LPS), the S-ROM Modular Knee system, and the P.F.C. Sigma system. The previously cleared indications for use for these systems are the following:

The LPS is intended for use in replacement of the mid-shaft portion of the femur, proximal, distal and/or total femur, and proximal tibia, especially in cases that require extensive resection and replacement. Specific diagnostic indications for use include:

- malignant tumors (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) requiring extensive resection and replacement;
- patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis, requiring extensive resection and replacement;
- revision cases for a failed previous prosthesis requiring extensive resection and replacement;
- severe trauma requiring extensive resection and replacement.

The LPS is also intended for use in bone loss post-infection, where the surgeon has elected to excise the bone and replacement is required.

The metaphyseal sleeve, the distal femoral component, the tibial components, and the non-porous coated straight and bowed stems are intended for cemented use only.

(CONTINUED ON THE NEXT PAGE)

Prescription Use XXXXX AND/OR Over-The-Counter Use _____
 (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

John G. Babb
(Division Sign-Off)

Division of General, Respiratory, and Neurological Devices

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(Posted November 13, 2003)

510(k) Number K040281

The S-ROM Modular Total Knee System was cleared as the "NOILES Posterior Stabilized Knee." The NOILES Posterior Stabilized Knee is indicated for use with PMMA bone cement in primary or revised cases in patients:

- who have reached skeletal maturity and
- for whom the surgeon has decided to resect both cruciate ligaments or whose cruciate ligaments are absent or incompetent due to the following conditions: rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, and arthritis secondary to a variety of diseases and anomalies, failure of a previous knee reconstruction procedure, trauma.

The P.F.C.® Sigma Knee System is indicated for use as a total knee replacement for patients suffering from severe pain and disability due to permanent structural damage in the knee joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, or pseudogout.

This damage may also be a result of trauma or failed prior surgical intervention.

The P.F.C.® Sigma Knee System is indicated for use with polymethylmethacrylate (PMMA) bone cement.